

Health Product Claims Alert

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July 29, 1999

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

To whom it may concern:

The Health Product Claims Alert respectfully submits this Citizen Petition requesting the Food and Drug Administration to take administrative action against E. Excel International.

Enclosed are the original and three copies of the Citizen Petition with supporting documents. The original also includes samples of E. Excel products obtained by the Health Product Claims Alert.

Sincerely,



John E. Buttolph
The Health Product Claims Alert

99P-2554

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**Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852**

Citizen Petition

The undersigned submits this petition under 21 C.F.R. §10.30 to request the Commissioner of Food and Drugs to take administrative action against E. Excel International, Springville, UT 84663.

A. Action Requested

The undersigned respectfully requests that the Commissioner of the Food and Drug Administration take the following administrative action against E. Excel International:

1. enjoin E. Excel from manufacturing, selling, and distributing its products until such time as it complies with the provisions of the Federal Food, Drug and Cosmetic Act;
2. require E. Excel to submit a public statement that its previous labels, labeling and other promotional materials contained unlawful, misleading or unsubstantiated health claims;
3. levy appropriate financial penalties and fees on E. Excel for its unlawful practices; and
4. require E. Excel to provide consumers who have purchased E. Excel's products the opportunity to refund their purchases.

E. Excel International is a multi-million dollar, direct sale dietary supplement company located in Springville, Utah. The company sells an assortment of herbal products and beverages in both domestic and overseas markets. Unfortunately, E. Excel promotes its products by relying heavily upon unsubstantiated drug claims.

The company was founded in 1989 by Jau-Fei Chen, who claims to have created a new science called "nutritional immunology," which she describes as a new "technology in food design." E. Excel promotes its products around this concept of "nutritional immunology." E. Excel International, *A Profile of Excellence*, 1997, p.15, 17 (Tab 1). In Ms. Chen's promotional materials, she asserts that if the cells of the immune system are properly nourished, they can "mount attacks on cancers and viruses and successfully defend the body against disease." Jau-Fei Chen, *Nutritional Immunology*, Bright Ideas Press, Provo, Utah, 1993, p.31 (Tab 2). Thus, according to the promotional products, an individual's efforts should be aimed at eating the proper foods to allow the immune system to function properly. Ms. Chen claims that the immune system then can be equipped to attack diseases "through proper nourishment and care." E. Excel International brochure, 1999, p.6 (Tab 3).

She asserts that most foods are tainted by pesticides and preservatives, and many supplements are toxic. And, she asserts that the only source of the proper foods that can nourish the immune system properly are from her company, E. Excel. Jau-Fei Chen, *Plant Foods & Immunology: A Scientific Approach*, Bright Ideas Press, Provo, Utah, p.45 (Tab 4).

A Health Product Claims Alert review of her products, promotional material and other labeling has revealed that E. Excel makes claims for these products that are clearly not permitted under the law.

This is not the first time that E. Excel has violated federal law. In 1992, Jau-Fei Chen and E. Excel were charged by the United States with a felony for mislabeling surgical gloves imported from China. She pled guilty and paid more than \$184,000 in fines. (A copy of pertinent criminal records is attached, Tab 5).

In 1989, she was warned by the Food and Drug Administration that her label claims for the product, True Balance, could make the product an illegal, unapproved drug. According to an FDA Form 483, dated September 18, 1989, Ms. Chen promised that she would redesign her product labels and send draft copies of her new labels to the FDA Denver office for review and comment. FDA Form 483, September 18, 1989, p.4. It does not appear that this ever happened. (A copy of this Form 483 is attached, Tab 6).

In August 1998, an FDA field inspector visited E. Excel's facilities in Springville, Utah. According to the FDA inspection report, the FDA inspector reported that the company did not have any marketing literature, even though the literature referenced in this petition, all of which was developed and printed by the company, is readily available through the company or its distributors.

This Citizen Petition will demonstrate that E. Excel utilizes a significant amount of marketing literature, which relies substantially on unapproved drug claims.

It is imperative that FDA take action against E. Excel. Failure to enforce the law against companies such as E. Excel has created a regulatory atmosphere that encourages and rewards individuals who violate the law and penalizes those who try to market their products legally. This failure on FDA's part not only endangers consumers in the United States, but also overseas, where E. Excel apparently sells a majority of its products. According to E. Excel's brochures, it sells its products "in over 10 nations." *The Excellent Word*, Volume 25, page 34 (Tab 7).

B. Statement of Grounds

1. Conventional Food or Dietary Supplement?

According to E. Excel's promotional materials and labeling, its products are either conventional foods or dietary supplements. For example, a company brochure states, "E. Excel products are unique in that they are *whole-plant foods*. ... We take pride in the fact that our products are safe, quality, *whole foods*..." E. Excel Promotional Brochure, p.3 (Tab 8) [emphasis added].

The promotional material that describes E. Excel's Daily Nutrition Pack similarly describes the product as a "whole food":

"The *Daily Nutrition Pack* is convenient and easy to use. It contains a 30-day supply of morning and evening packets designed to be used on a daily basis. Each *Daily Nutrition Pack* contains a unique combination of *whole foods* all specially formulated to nourish the major systems of the body.... In order to maintain optimum health, the *Daily Nutrition Pack* should be eaten every day along with any of the other E. Excel products you wish to add to your diet." *E. Excel Product Information*, p.9 (Tab 9) [emphasis added].

At the same time, E. Excel clearly positions some of its products to fall under the dietary supplement regulatory framework. For example, the products Ji-Lin Ginseng, Circle, Noco, S*T, and Concenergy have "Dietary Supplement" displayed on the label. This identification is required under DSHEA for products being marketed as dietary supplements. 21 U.S.C. § 321(ff). In addition, each of the above-referenced products displays a supplement panel on its label, which conforms with the regulations set forth for products being marketed as dietary supplements. 21 C.F.R. § 101.36.

In other cases, however, products are marketed without the required label information for either foods or dietary supplements. For example, the product Phytocopia, which is marketed as a whole food cookie, does not contain the nutrition facts panel required for foods. 21 C.F.R. §

101.9. The product Nutriall, which is marketed as an herbal drink mix, also does not contain the required nutrition facts panel, nor does it meet the label requirements under DSHEA.

2. E. Excel's Promotional Materials Rely Heavily Upon the Use of Unsubstantiated Drug Claims.

Although it is unclear whether E. Excel intends for its products to be treated as foods or dietary supplements, it clearly markets them as drugs. A company may not make drug claims for foods. Moreover, under the Dietary Supplement Health and Education Act ("DSHEA"), a manufacturer may make "statements of nutritional support," if certain conditions are met. However, DSHEA makes clear that a statement included in labeling may not claim to "diagnose, mitigate, treat, cure or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6).

A review of E. Excel's product labels and labeling has revealed that the company relies heavily upon the use of unsubstantiated drug claims. The company repeatedly implies that its products can not only prevent but cure diseases such as diabetes, cancer, and AIDS. If not stopped, these business practices could endanger the lives of uninformed consumers, who are encouraged to replace conventional therapies and remedies with a strict reliance on an expensive array of unproven products.

The company sells its products around what its founder, Jau-Fei Chen, describes as the new science of "nutritional immunology," which she calls "a technology in food design." In her books, she explains the basis of this new science. For example, in her book, *Plant Foods & Immunology: A Scientific Approach*, the following assertion is made on page 49:

"Ever since the discovery of antibiotics, the scientific field has become focused on the development of drugs that might 'cure' diseases. However, scientists are beginning to discover that drugs and chemical substances are not the 'cure-all' they were once thought to be. It is actually the body's own defense system that plays a critical role in treating disease. *Scientists are discovering that when the immune system functions properly, it can combat or cure almost any disease.* Thus, all of our efforts should be aimed at eating proper foods that allow the immune system to function efficiently."

Jau-Fei Chen, *Plant Foods & Immunology: A Scientific Approach*, Bright Ideas Press, Provo, Utah, 1996 (Tab 4). [emphasis added]

As highlighted above, the foundation upon which E. Excel sells its products is that proper nutrition can "combat or cure almost any disease." *A Profile of Excellence*, E. Excel International, 1997, p. 15 (Tab 1). Interestingly, a scan of the company's promotional materials

clearly suggests that only E. Excel's products offer this "proper nutrition."

While E. Excel's materials contain general disclaimers such as "...the job of diagnosing, treating, and curing disease should be left to professionals, such as medical doctors," collectively the materials encourage a much different result. In fact, all of the promotional materials are based on the theory that E. Excel's products are an alternative to traditional medical treatments. The following examples illustrate the kind of illegal drug claims that are being made by E. Excel through its promotional materials:¹

a. Diabetes

The following quote is from an E. Excel promotional publication called *The Excellent Word*, which discusses diabetes and promotes the company's "cactus nectar", Millennium:

"As discovered through research, certain elements of the cactus plant can increase the body's sensitivity to insulin. In some areas of the world, cactus is actually used as a treatment for insulin-independent diabetes as it possesses properties which can lower blood glucose levels.... Such research demonstrates the usefulness of cactus as a nutritional plant food which can be used as a remedy for insulin-independent diabetes." *The Excellent Word*, v.23, p.16 (Tab 10).

b. Cancer

The following claims are taken from promotional materials for Phytocopia, which is a cookie made from more than "40 different fruits and vegetables" that are rich in phytochemicals. According to this pamphlet, these phytochemicals can prevent tumors, inhibit lung cancer, and prevent breast cancer.

"...sulphoraphane has been discovered to not only prevent breast cancer in laboratory animals, but to also trigger the process that removes carcinogens from cells before they can cause damage." *Phytocopia promotional pamphlet*, p.2 (Tab 12).

"In addition to inhibiting cancerous cells, phytochemicals are also believed to prevent dietary fat from promoting tumors, reduce the probability of colon, breast, and prostate cancer, reduce the growth of microorganisms, and improve blood lipids and serum cholesterol levels." *A Profile of Excellence*, E. Excel International, 1997, p. 17 (Tab 1).

Four other company products, Enjoi, Herba, Li-Dan, and Nutriall, contain herbal ingredients that reportedly "inhibit the growth of cancer cells," "fight against cancer," and "contain anti-cancer properties." *E. Excel Product Information*, p.12-15² (Tab 9).

¹ Copies of some of the E. Excel promotional materials referenced above are attached.

² "[Ganoderma] has even been shown to inhibit the growth of cancer cells...." *E. Excel Product Information*, p. 12-13 (relating to Enjoi) (Tab 9).

c. Cholesterol

Two E. Excel products are reported to contain ingredients that reduce cholesterol levels. For example, the product Millennium is promoted as follows:

“It was found that cactus extract can decrease cholesterol levels.” *The Excellent Word*, v.23, p.24 (Tab 10).

The product, Circle, which is described as a food designed specifically to enhance and regulate the circulatory process, maintain flexibility in the circulatory system, and promote balance in the entire body, contains Hawthorn which, among other things, “...has been used to treat insomnia, nervousness, high-blood pressure and high cholesterol.” *E. Excel Product Information*, p.22 (Tab 9).

d. Gastric Ulcers

The product D*I, which is promoted as “enhancing the functions of the digestive system,” reportedly contains wild ginger, which E. Excel claims can “prevent gastric ulcers.” *E. Excel Product Information*, p.24 (Tab 9).

e. Problems Associated with the Menstrual Cycle and Menopause

The product Dong-Quai, which E. Excel claims is often referred to as the “queen of female herbs,” reportedly can heal a variety of ailments:

“Quai Concentrate strengthens the brain and nervous system and helps with the many problems (hot flashes, sweating, fatigue, nervousness, depression, insomnia, stomach upsets, chills, headaches, etc.) associated with the menstrual cycle and menopause.” *E. Excel Product Information*, p.25 (Tab 9).

f. Parkinson’s Disease and Other Problems Associated with the Nervous System

The product S*T is reportedly designed to address problems associated with the nervous system, including Parkinson’s Disease:

“S*T is designed to nourish the Nervous System, including the brain, spinal cord, nerves and sensory receptors.... If the nervous system is not properly balanced, complications can occur within the body, including insomnia, nervousness, stress, headaches, depression, and forgetfulness.... More debilitating diseases, such as Parkinson’s disease are also products of nervous system dysfunction.” *E. Excel Product Information*, p.28 (Tab 9).

“Special components found within the orange peel play an important role in the fight against cancer.” *E. Excel Product Information*, p.14, (relating to Li-Dan) (Tab 9).

“[contains tangerine peel, which] contains cancer inhibiting properties and essential oils.” *E. Excel Product Information*, p. 16 (relating to Nutriall) (Tab 9).

g. AIDS

E. Excel has a product called "ACT," which clearly sounds like "AZT" and is purported to "nourish the immune system." E. Excel promotional literature claims that if the immune system is not functioning properly, "the body becomes susceptible to many ailments, such as allergies, sinus problems, and even potentially fatal autoimmune diseases." *E. Excel Product Information*, p.20 (Tab 9). The company's promotional material claims that ACT will "strengthen and enhance the immune system, enabling the body to defend itself against disease." *Ibid.* Moreover, ACT is marketed by the company as a product for AIDS patients.

Clearly, the product information referenced above alludes to ACT's alleged ability to fight AIDS. Moreover, one of E. Excel brochures asserts that the United States government has purchased ACT to treat patients with AIDS.³ The following are additional excerpts from E. Excel's promotional materials:

"It is known that many cancer and AIDS patients die of opportunistic deaths because their immune systems are suppressed. Immune enhancement could bring patients' immune systems to a point where they are able to fight their own battles and free themselves from these dreadful diseases." Jau-Fei Chen, *Nutritional Immunology*, Bright Ideas Press, Provo, Utah, 1993, p.43 (Tab 2).

and,

"In a weakened state the body can easily fall prey to everything from allergic reactions and food sensitivities to the deadliest of diseases—including such killers as cancer and AIDS.... When the cells of the immune system are properly nourished, they can mount attacks on cancers and viruses and successfully defend the body against disease." Jau-Fei Chen, *Nutritional Immunology*, Bright Ideas Press, Provo, Utah, 1993, p.31 (Tab 2).

h. Disease Treatment and Prevention Chart

One of the more offensive E. Excel promotional brochures contains a chart that lists various diseases in one bracket and the E. Excel product that should be taken to treat these ailments in the corresponding bracket. It should be noted that this page contains the following disclaimer:

"This information contained within this material is included for reference and educational purposes only. It is not intended as a substitute for the advice of a qualified medical professional. E. Excel International does not condone or advocate self-diagnosis or self-medication in any way. If you have a condition which requires medical diagnosis and treatment, it is important that you visit a licensed health professional. The opinions expressed by authors and contributing distributors do not necessarily reflect the opinions

³ "The U.S. government has purchased E. Excel product --- ACT, to provide to AIDS patients." E. Excel International, *E. Excel Product Information*, p.1 (Tab 11).

of E. Excel International.” *E. Excel Product Information*, p. 14
(Tab 11).

Unfortunately for E. Excel International, there is nothing in either DSHEA or the Federal Food, Drug and Cosmetic Act that would make the company’s illegal drug claims suddenly legal by including the above-displayed disclaimer.

The chart in question contains one bracket titled, “Symptom of Illness.” The corresponding bracket is titled, “E. Excel Product Recommendation.” The following examples are taken from the chart:

Symptom of Illness

rickets, osteoporosis, arthritis, gout,
bursitis, cramp, atrophy, backpain,
tendonitis [sic], multiple sclerosis, etc.

muscle pain, spasms, insomnia,
nervousness, stress, headaches,
depression, forgetfulness,
Parkinson’s disease, strokes, etc.

thyroid imbalance, acne, anorexia,
bulimia, graves’ disease (exophthalmic
goiter), diabetes, acromegaly, etc.

irregular heartbeat (arythmia [sic]/
palpitations, high blood pressure,
cholesterol, hypertension,
arteriosclerosis, etc.

peptic ulcers, gallstones, parasites,
diarrhea, vomiting, constipation,
hemorrhoids, hepatitis

allergies, tumors, cancers, autoimmune
disease, infections, etc.

pneumonia, tuberculosis, allergies, colds
flu, asthma, bronchitis, emphysema,
mucus, sore throats, etc.

kidney stones, bladder infections, kidney
infections, etc.

E. Excel Product Recommendation

Daily Nutrition Pack, ART, ACT,
S*T

Daily Nutrition Pack, S*T,
Concenergy, Pearl (female)

Daily Nutrition Pack,
Concenergy, ACT, Pearl (female),
Refresh

Daily Nutrition Pack, Circle,
Herba

Daily Nutrition Pack, D*I, Li-Dan,
Refresh

Daily Nutrition Pack, ACT,
Millennium

Daily Nutrition Pack, NOCO
ACT

Daily Nutrition Pack, Concenergy,
Refresh, Li-Dan

irregular menstruation, endometriosis,
infertility, menopausal symptoms,
impotence, prostate problem, etc.

Male: Daily Nutrition Pack,
Concenergy, Ginseng,
Female: Daily Nutrition Pack,
Pearl, Dong Quai, S*T

acne, cysts, baldness, eczema, skin
diseases

Daily Nutrition Pack, D*I, ACT
Li-Dan, Refresh, Pearl (female)
Concenergy (male)

glaucoma, cataract, keratitis, buzzing
in the ears, weak of hearing

Daily Nutrition Pack, S*T, ACT,
Refresh

E. Excel Product Information, p. 14 (Tab 11).

3. Statement Required for Nutritional Support Claims

The Dietary Supplement Health and Education Act requires manufacturers that make statements of nutritional support about their products to prominently display the following statement, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” 21 U.S.C. § 343(r)(6)(C).

The FDA regulations that implement this statutory provision state that this disclaimer is to be placed adjacent to the statement of nutritional support or linked to the statement with a symbol (e.g., an asterisk). The regulations further provide that in company pamphlets and catalogs, the disclaimer is to appear on each panel or page where there is such a statement. Further, the disclaimer is to be set off in a box if it is not directly adjacent to the statement. The disclaimer is to appear in boldface type in typesize no smaller than one-sixteenth inch. 21 C.F.R. 101.93(d)-(e).

The Health Product Claims Alert did not find one disclaimer in E. Excel’s labels, labeling, catalogs, brochures or any other promotional material. This is significant because E. Excel asserts that its products have been scrutinized and approved by regulatory agencies in over 10 countries. In a recent copy of *The Excellent Word*, which is an E. Excel publication, the company states:

“Another benefit of E. Excel’s international status is worldwide inspection. Because the E. Excel products are sold in over 10 nations, they are subject to strict testing by each of those countries, and are held to both exacting regulations and high standards of quality. Consumers can place great confidence in our products, knowing they have passed inspections worldwide.” *The Excellent Word*, Volume 25, page 34 (Tab 7).

4. Substantiation

It is difficult to understand how the FDA field investigator who inspected E. Excel's facilities could not find any promotional materials about E. Excel's products. CFN: 1721662, August 19-20, 1998, Jill Mielziner, Investigator (Tab 13). This is especially alarming since the chart referenced in the preceding section and many of the claims mentioned in this Citizen Petition were taken from promotional material delivered by E. Excel this past week to my organization.

Clearly, E. Excel produces a considerable amount of promotional materials and other labeling for its products. As demonstrated above, these materials contain a substantial amount of unlawful drug claims. Moreover, the FDA field investigator did not mention finding any substantiation for *any* of the claims made by E. Excel in its labeling. This is a clear violation of section 403(r) of the Food, Drug and Cosmetic Act, as amended by DSHEA, which provides, that a statement of nutritional support for a dietary supplement made be made only if, among other things, "the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading..." 21 U.S.C. § 343(r)(6). Based on the FDA field investigator's report, it does not seem likely that E. Excel has any substantiation for its health claims.

In addition, FDA regulations require that a manufacturer, packer or distributor of a dietary supplement that makes a statement of nutritional support must notify the Office of Special Nutritionals that such statement is being made and that the company has substantiation that the statement is truthful and not misleading, no later than 30 days after being marketed. 21 C.F.R. § 101.93(a)(1). If the company is alleging that various drug claims are permissible statements of nutritional support, there is no evidence provided to consumers that these notices are being provided to the FDA.

C. ENVIRONMENTAL IMPACT

An environmental impact statement is not required for this Citizen Petition pursuant to 21 C.F.R. § 25.30(a) and (d). An environmental impact statement is not needed for the following:


"Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments." 21 C.F.R. § 25.30(a)

and,

"Destruction or disposition of any FDA-regulated article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, is in compliance with all Federal, State, and local requirements." 21 C.F.R. § 25.30(d)

D. CERTIFICATION

The undersigned to this petition certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.



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List of Attachments

Tab	Attachment
1	E. Excel, <i>A Profile of Excellence</i> , 1997, p.15, 17
2	Jau-Fei Chen, <i>Nutritional Immunology</i> , Bright Ideas Press, Provo, Utah, 1993, p.31, 43
3	E. Excel International brochure, 1999, p.6
4	Jau-Fei Chen, <i>Plant Foods & Nutritional Immunology: A Scientific Approach</i> , Bright Ideas Press, Provo, Utah, p.45, 49
5	Jau-Fei criminal records
6	FDA Form 483, September 18, 1989
7	<i>The Excellent Word</i> , Volume 25, p.34
8	E. Excel Promotional brochure, p.3
9	<i>E. Excel Product Information</i> , p.9, 12-15, 16, 20, 22, 24, 25, 28
10	<i>The Excellent Word</i> , Volume 23, p.16, 24
11	<i>E. Excel Product Information</i> , p.1
12	<i>Phytocopia promotional pamphlet</i> , p.2
13	Jill Mielziner's report, August 19-20, 1999, CFN: 1721662